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PHA 42640.1 (01382/1/US)
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of Diane T. Stephenson et al.

Serial No. 10/828,990

Filed April 21, 2004

For COMPOSITIONS OF A CYCLOOXYGENASE-2 SELECTIVE INHIBITOR AND A
POTASSIUM ION CHANNEL MODULATOR FOR THE TREATMENT OF
CENTRAL NERVOUS SYSTEM DAMAGE

July 28, 2004

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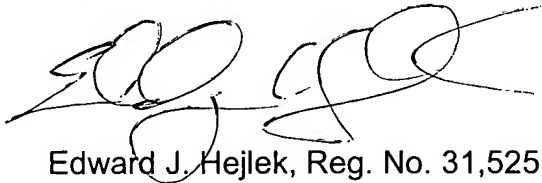
INFORMATION DISCLOSURE STATEMENT

In accordance with 37 C.F.R. 1.97 and 1.98 and MPEP 609, and in compliance with the duty of disclosure set forth in 37 C.F.R. 1.56, applicants submit the attached PTO/SB/08A for consideration by the Patent and Trademark Office in the above-entitled application and to be made of record therein. In accordance with the OG notice of August 5, 2003 partially waiving the requirements of 37 C.F.R. 1.98(a)(2)(i), copies of the U.S. patent documents are not supplied. Applicants submit herewith copies of the foreign patent documents and literature references.

This Information Disclosure Statement is being submitted pursuant to 37 C.F.R. §1.97(b) in that applicants believe that it is being filed prior to the mailing date of the first Office action on the merits. Accordingly, neither a statement nor fee under 37 C.F.R. §1.97(c) or (d) is required. However, if an Office action was issued prior to the

date of mailing of this Information Disclosure Statement, the Commissioner is hereby authorized to charge any required fees regarding this Information Disclosure Statement to Deposit Account No. 19-1345.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'EJH', with a horizontal line extending to the right.

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EJH/cms
*Enclosures

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PTO/SB/08A				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Application Number	10/828,990
				Filing Date	April 21, 2004
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				First Named Inventor	Diane T. Stephenson
				Group Art Unit	
				Examiner Name	
	1	of	4	Attorney Docket No.	PHA 42640.1 (01382/1/US)



U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code ² (if known)		
	1	5,466,823		Talley et al	11/14/1995
	2	5,521,207		Graneto	05/28/1996
	3	5,633,272		Talley et al	05/27/1997
	4	5,932,598		Talley et al	08/03/1999
	5	6,034,256		Carter et al	03/07/2000
	6	6,077,850		Carter et al	06/20/2000

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	T ⁶
		Office	Number ⁴	Kind Code ² (if known)			
	7	WO	91/08760		Brigham and Women's Hospital	06/27/1991	
	8	WO	92/16192		Amgen Inc.	10/01/1992	
	9	WO	98/03484		Merck Frosst Canada Inc.	01/29/1998	
	10	WO	00/24719		Abbott Laboratories	05/04/2000	

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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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OTHER ART - NON PATENT LITERATURE DOCUMENTS				
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶	
7	11	ALBERS, "Rationale for Early Intervention in Acute Stroke", American Journal of Cardiology, 1997, 804(4C): 4d-10d		
J	12	GROVER et al, "Anti-Ischemic Effects of the Potassium Channel Activators Pinacidil and Cromakalim and the Reversal of these Effects with the Potassium Channel Blocker Glyburide", Journal of Pharmacology and Experimental Therapeutics, 1989, 251(1): 98-104		
	13	IADECOLA et al, "Reduced Susceptibility to Ischemic Brain Injury and N-Methyl-D-Aspartate-Mediated Neurotoxicity in Cyclooxygenase-2-Deficient Mice", PNAS, 2001, 98: 1294-1299		
5	14	IADECOLA et al, "Inducible Nitric Oxide Synthase Gene Expression in Brain Following Cerebral Ischemia", Journal of Cerebral Blood Flow Metabolism, 15: 378-384, 1995		
5	15	IADECOLA et al, "Inducible Nitric Oxide Synthase Gene Expression in Vascular Cells After Transient Focal Cerebral Ischemia", Stroke 27: 1373-1380		
	16	KRATZER et al, "Simulation of Primary Haemostasis in Vitro", Haemostasis, 1985, 15:357-362		
	17	LAPCHAK et al, "Neuroprotection by the Selective Cyclooxygenase-2 Inhibitor SC-236 Results in Improvements in Behavioral Deficits Induced by Reversible Spinal Cord Ischemia", 2001, Stroke, 32(5): 1220-1230		
	18	LIN et al, "Effect of Brain Edema on Infarct Volume in a Focal Cerebral Ischemia Model in Rats", Stroke, 24: 117-121, 1993		
	19	LIPPERT et al, "Over-Additive Protective Effect of Dizocilpine and NBQX Against Neuronal Damage", Eurpoean Journal of Pharmacology, 1994, 253: 207-213		

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	20	LONGA et al, "Reversible Middle Cerebral Artery Occlusion Without Craniectomy in Rats", Stroke, 20: 84-91, 1989	
	21	NAGAYAMA et al, "The Cyclooxygenase-2 Inhibitor NS-398 Ameliorates Ischemic Brain Injury in Wild-Type Mice but not in Mice with Deletion of the Inducible Nitric Oxide Synthase Gene", Journal of Cerebral Blood Flow and Metabolism, 1999, 19(11): 1213-19	
	22	NEWMAN, "Aerosols and the Lung: Clinical and Experimental Aspects", Chapter 9 - "Therapeutic Aerosols", Butterworths, London, England, 1984, p. 197-224	
	23	NOGAWA et al, "Cyclo-Oxygenase-2 Gene Expression in Neurons Contributes to Ischemic Brain Damage", The Journal of Neuroscience, April 15, 1997, 17(8): 2746-2755	
	24	OGAWA et al, "Super-Delayed Changes of Muscarinic Acetylcholine Receptor in the Gerbil Hippocampus Following Transient Ischemia", Advances in Experimental Medicine and Biology, 287: 343-347	
	25	OGAWA et al, "Post-Ischemic Administration of Bifemelane Hydrochloride Prohibits Ischemia-Induced Depletion of the Muscarinic M ₁ -Receptor and its mRNA in the Gerbil Hippocampus", Brain Research, 591: 171-175	
	26	PURCELL et al, "Potassium Channel Openers in Myocardial Ischaemia - Clinical Experience with Nicorandil", Journal of Clinical Cardiology, 1999, 2: 12-14	
	27	SARGENT et al, "Effect of Potassium Channel Blockade on the Anti-Ischemic Actions of Mechanistically Diverse Agents", Journal of Pharmacol Experimental Therapeutics, 1991, 259(1): 97-103	
	28	STEIN, J. http://www.pslgroup.com/dg/22068A.htm , "ANA: Fampridine May Help Patients with Spinal Cord Injury", October 16, 2002	
	29	TANAKA et al, "Post-Ischemic Administration of the Acetylcholinesterase Inhibitor ENA-713 Prevents Delayed Neuronal Death in the Gerbil Hippocampus" Neurochemical Research, 1995, 20(6):663-667	
	30	TURSKI et al, "ZK200775: A Phosphonate Quinoxalinedione AMPA Antagonist for Neuroprotection in Stroke and Trauma", PNAS, 1998, 95: 10960-10965	

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	31	VILA et al, "Proinflammatory Cytokines and Early Neurological Worsening in Ischemic Stroke", Stroke, 2000, 31: 2325-2329	
	32	ZHANG et al, "Reduction Focul Cerebral Ischemic Damage by Delayed Treatment with Nitric Oxide Donors", Journal of Cerebral Blood Flow Metabolism, 1994, 14: 574-580	
	33	ZHANG et al, "Aminoguanidine Ameliorates and L-Arginine Worsens Brain Damage From Intraluminal Middle Cerebral Artery Occlusion", 1996, Stroke 27: 317-323	

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